K073517

510(K) Summary: H-LINK™ Integrated Rod

JAN - 3 2008

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

Device Name: H-LINK™ Integrated Rod

Classification: Per 21 CFR as follows:
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
Product Codes MNH, MNI, NKB.
Regulatory Class II and III, Panel Code 87.

Predicate(s): Globus Medical REVERE™ Stabilization System
K061202, SE date July 20, 2006
Globus Medical PROTEX® Stabilization System
K040442, SE date May 20, 2004
K052069, SE date August 17, 2005
Product Codes MNH, MNI, NKB included
Regulatory Class II and III, Panel Code 87.

Device Description:
The H-LINK™ Integrated Rod is a unitary implant that combines a t-connector with two rods. The rod diameter is 5.5mm or 6.35mm and the t-connector feature adjusts laterally. The 5.5mm H-LINK™ Integrated Rod can be used with a 5.5mm rod titanium posterior pedicle screw system, such as the REVERE™ Stabilization System. The 6.35mm H-LINK™ Integrated Rod can be used with a 6.35mm rod titanium posterior pedicle screw system, or with the PROTEX Stabilization System, which utilizes 6.0mm or 6.5mm rods. These implants are available in a variety of sizes to accommodate individual patient anatomy. H-LINK™ is intended for posterior use only and is positioned and secured into bilateral pedicle screws.

H-LINK™ is composed of titanium alloy as specified in ASTM F136 and F1295. Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be connected to stainless steel implants.

Intended Use:
The H-LINK™ Integrated Rod, when used with posterior pedicle screws, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with

degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the H-LINK™ Integrated Rod is intended for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

Basis of Substantial Equivalence:
The H-LINK™ Integrated Rod is similar to predicate REVERE™ and PROTEX® Stabilization System implants system with respect to technical characteristics, performance, and intended use. Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 is presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2008

Globus Medical Inc.
% Dr. Kelly J. Baker
Director, Clinical Affairs & Regulatory
2560 General Armistead Ave.
Audubon, PA 19403

Re: K073517
Trade/Device Name: H-Link™ Intergrated Rod
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNH, MNI
Dated: December 13, 2007
Received: December 14, 2007

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: H-LINK™ Integrated Rod

INDICATIONS:

The H-LINK™ Integrated Rod, when used with a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

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Prescription Use __X____ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073517